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UNITED STATES DISTRICT COURT
DISTRICT OF UTAH

SCOTT SMITH and
CINDY SMITH,
Plaintiffs,

v.

GENERAL ELECTRIC COMPANY;
GE HEALTHCARE, INC.;
GE HEALTHCARE AS;
BAYER CORPORATION;
BAYER HEALTHCARE LLC;
BAYER HEALTHCARE PHARMACEUTICALS, INC.;
BERLEX LABORATORIES, INC. n/k/a BERLEX, INC.;
SCHERING, AG;
BAYER AG;
BAYER SCHERING PHARMA AG;
SCHERING BERLIN, INC.;
BAYER GESELLSCHAFT FUR BETEILIGUNGEN MBH;
MALLINCKRODT, INC.;
BRACCO DIAGNOSTICS INC;
BRACCO RESEARCH USA, INC.;
ALTANA PHARMA AG; and

COMPLAINT AND JURY DEMAND

Case: 2:08cv00360
Assigned To : Benson, Dee
Assign. Date : 5/6/2008
Description: Smith et al v. General Electric Company et al

NYCOMED INTERNATIONAL MANAGEMENT GmbH

Defendants.

Plaintiffs, by and through undersigned counsel, and for their Complaint and Jury Demand against Defendants, allege upon information and belief as follows:

PARTIES

1. Plaintiffs are married and at all times relevant have jointly resided in Magna, UT.

2. Plaintiffs allege an amount in controversy in excess of Seventy Five Thousand Dollars ($75,000.00), exclusive of interest and costs.

3. Defendant General Electric Company is a New York Corporation with its principal place of business at 3135 Easton Turnpike, Fairfield, Connecticut 06431. Defendant General Electric Company is a resident of both New York and Connecticut. Defendant General Electric Company is the parent company of Defendant GE Healthcare AS and GE Healthcare, Inc.

4. Omniscan, one of the products in question in this suit, is identified by General Electric Company in its packaging that it is a product of "GE Healthcare," which is a unit/division of General Electric Company. "GE Healthcare" is prominently identified on the Omniscan packaging/prescribing information, alongside the "GE" monogram. Omniscan is identified as a trademark of GE Healthcare. "GE" and the GE monogram are trademarks of the General Electric Company. The GE Healthcare website, which includes detailed product

information concerning Omniscan, is copyrighted by General Electric Company. General Electric Company does business as GE Healthcare, including the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into United States interstate commerce, the drug Omniscan.

5. At all times relevant, Defendant General Electric Company, and/or its corporate predecessors, was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into the stream of commerce, directly and indirectly through third parties or related entities, the drug Omniscan.

6. Defendant GE Healthcare AS is a Norwegian corporation with its principal place of business in the Kingdom of Norway. Defendant GE Healthcare AS is a subsidiary of General Electric Company. Omniscan's package insert/prescribing information identifies the putative manufacturer of Omniscan as GE Healthcare AS.

7. At all times relevant, Defendant GE Healthcare AS, and/or its corporate predecessors, was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into United States interstate commerce, directly and indirectly through third parties or related entities, the drug Omniscan.

8. Defendant GE Healthcare, Inc. is a Delaware corporation with its principal place of business at 101 Carnegie Center, Princeton, New Jersey. Defendant GE Healthcare, Inc. is a resident and citizen of both Delaware and New Jersey. Defendant GE Healthcare, Inc. is a subsidiary of General Electric Company. Omniscan's package insert identifies the putative distributor of Omniscan as GE Healthcare, Inc.

9. At all times relevant, Defendant GE Healthcare, Inc., and/or its corporate predecessors, was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, directly and indirectly through third parties or related entities, the drug Omniscan.

10. Upon information and belief and at the relevant times, Omniscan was distributed and sold in the United States by GE Healthcare, Inc. and was manufactured by GE Healthcare AS.

11. Defendants General Electric Company, GE Healthcare, Inc., and GE Healthcare AS will be collectively referred to in this Complaint as the "GE Defendants."

12. Defendant Bayer Corporation is an Indiana Corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Defendant Bayer Corporation is a resident and citizen of both Indiana and Pennsylvania.

13. Defendant Bayer Healthcare LLC is a Delaware limited liability company with its principal place of business at P.O. Box 2466, Berkeley, California. Defendant Bayer Healthcare LLC is a resident and citizen of both Delaware and California.

14. Defendant Bayer Healthcare LLC is a corporate successor to Berlex Laboratories, Inc. and, as such, is obligated for its predecessor's liabilities. Berlex Laboratories, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug Magnevist.

15. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business at 6 West Belt, Wayne, New Jersey. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a resident and citizen of both Delaware and New Jersey. Defendant Bayer Healthcare Pharmaceuticals, Inc. is the U.S.-based pharmaceuticals unit of Bayer Health Care LLC and is a division of Bayer AG.

16. Bayer Schering Pharma AG is a foreign company domiciled in Germany.

17. Defendant Schering, AG is the predecessor to Bayer Shering Pharma AG and is a foreign company domiciled in Germany.

18. Defendant Berlex Laboratories, Inc., n/k/a Berlex, Inc., based in Montville, New Jersey, was the U.S. arm of Schering, AG.

19. Schering Berlin, Inc. is based and/or has its principal place of business in Montville, New Jersey, and is in the business of pharmaceutical preparation and manufacturing.

20. Bayer Gesellschaft fur Beteiligungen mBH, is a foreign company domiciled in Germany.

21. Prior to 2006, Berlex Laboratories, Inc., n/k/a Berlex, Inc. and Schering, AG were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the diagnostic agent Magnevist.

22. Defendant Bayer AG bought Schering, AG in 2006. Defendants Bayer Corporation, Bayer AG, Bayer Schering Pharma AG, Bayer Healthcare LLC, and Bayer

Healthcare Pharmaceuticals, Inc. are corporate successors to Berlex Laboratories, Inc. and Shering, AG and, as such, are obligated for their predecessors' liabilities.

23. Defendant Bayer AG is a company domiciled in Germany and is the parent/holding company of all other Bayer Defendants.

24. Defendants Bayer Healthcare Pharmaceuticals, Inc., Bayer AG, Bayer Schering Pharma AG, Bayer Healthcare LLC, Schering, AG, Bayer Corporation, Schering Berlin, Inc., Bayer Gesellschaft fur Beteiligungen mBH, and Berlex Laboratories, Inc., n/k/a Berlex, Inc., will be collectively referred to in this Original Petition as the "Bayer Defendants."

25. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a corporate successor to Berlex Laboratories, Inc. (Berlex) and, as such, is obligated for its predecessor's liabilities. Berlex was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug Magnevist (gadopentetate dimeglumine).

26. At all times relevant, the Bayer Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, and into the State of Utah, either directly or indirectly through third parties or related entities, the diagnostic agent Magnevist (gadopentetate dimeglumine).

27. Defendant Mallinckrodt, Inc. ("Defendant Mallinckrodt") is a Delaware corporation with its principal place of business at 675 McDonnell Blvd., St. Louis, Missouri.

Defendant Mallinckrodt is a resident and citizen of both Delaware and Missouri. Defendant Mallinckrodt is a subsidiary of Tyco Healthcare Group LP.

28. At all times relevant, Defendant Mallinckrodt was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the diagnostic agent Optimark.

29. Defendant Bracco Diagnostics Inc. is a Delaware corporation with its principal place of business in Princeton, New Jersey.

30. Upon information and belief, at all times relevant, Defendant Bracco Diagnostics Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the diagnostic agents MultiHance and ProHance.

31. Upon information and belief, Defendant Bracco Research USA, Inc. is a Delaware corporation, with its principal place of business in Princeton, New Jersey.

32. Upon information and belief, at all times relevant, Defendant Bracco Research USA, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the diagnostic agents MultiHance and ProHance.

33. Upon information and belief, Defendant ALTANA Pharma AG is a German company with its principal place of business in Germany. Defendant ALTANA Pharma AG manufactured MultiHance and/or ProHance for Bracco Diagnostics Inc.

34. Upon information and belief, at all times relevant, Defendant ALTANA Pharma AG was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the diagnostic agents MultiHance and ProHance.

35. Defendant Nycomed International Management GmbH ("Nycomed") is a Swiss company domiciled in Switzerland. Defendant Nycomed bought ALTANA Pharma AG in 2006. Defendant Nycomed is corporate successor to ALTANA Pharma AG and, as such, is obligated for its predecessor's liabilities.

36. Defendants Bracco Diagnostics Inc., Bracco Research USA, Inc., ALTANA Pharma AG and Nycomed will be collectively referred to in this Complaint and Jury Demand as the "Bracco Defendants."

37. At all times relevant, the Bracco Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the diagnostic agents MultiHance and ProHance.

38. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

39. The Court has personal jurisdiction over Defendants consistent with the laws of the State of Utah and the United States Constitution because Defendants caused tortious injury in the State of Utah by an act or omission outside the State of Utah by virtue of Defendants' regularly conducted business in the State of Utah from which they derive substantial revenue.

40. Venue in this district is appropriate under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in the district as Plaintiff Scott Smith was administered the offending contrast dye in this district and suffered injury in this district.

GENERAL ALLEGATIONS

41. Magnevist is an injectable paramagnetic contrast agent used for magnetic resonance imaging and arteriography. It is a patented, proprietary formulation that contains the metal gadolinium which is highly toxic in its free state. Magnevist, the chemical name of which is gadopentetate dimeglumine, was represented by the Bayer Defendants to be safely and effectively indicated for intravenous administration to facilitate the visualization of cranial and spinal anatomy as well as tumors, lesions, and immediately adjacent areas. Magnevist was further represented by the Bayer Defendants to be superior to two of its competitors (Omniscan and OptiMARK) in its thermodynamic and conditional stability, its low volume of excess chelate, and its ability to prevent the release of gadolinium.

42. Berlex obtained FDA approval of its New Drug Application (App. No. 019596) for Magnevist (gadopentetate dimeglumine) on June 2, 1988.

43. In 2006, Bayer AG, which has its legal domicile in Berlin, completed its acquisition of Schering, AG. Berlex was a U.S. affiliate of Schering, AG. Bayer AG is a holding company that owns and operates Defendants Bayer Healthcare LLC and Bayer Healthcare Pharmaceuticals, Inc.

44. Magnevist (gadopentetate dimeglumine) is cleared from the body solely by glomerular filtration in the kidneys. As a result, it has a prolonged half-life in patients with renal insufficiency and who, therefore, are at increased risk for adverse health effects in connection with Magnevist (gadopentetate dimeglumine) administration.

45. At all times relevant hereto, the Bayer Defendants knew, or should have known, about the significant health risk of Magnevist (gadopentetate dimeglumine) administration to patients with renal insufficiency including, but not limited to, the risk of nephrogenic fibrosis in the skin and other body organs. The Bayer Defendants knew, or should have known, of the need to prevent the gadolinium contained in its product from becoming free in the body of humans injected with Magnevist through the use of, among other things, proper design, testing, and manufacturing.

46. At all times relevant hereto, the Bayer Defendants knew, or should have known, that there were safer, alternative designs for paramagnetic contrast agents that would prevent or minimize the risk of gadolinium becoming free in the bodies of humans.

47. Nephrogenic Systemic Fibrosis (NSF), also known as Nephrogenic Fibrosing Dermopathy (NFD), has been reported in medical literature since 2000.

48. It has always been the case that this clinical entity now known as NSF/NFD develops in patients with renal insufficiency who have been given an injection of gadolinium-based contrast agent such as Magnevist (gadopentetate dimeglumine).

49. Magnevist (gadopentetate dimeglumine) is chemically distinct from other gadolinium-based contrast agents in that it more easily permits the release of toxic free gadolinium under expected physiologic conditions in patients with renal insufficiency who received it.

50. At all times relevant hereto, the Bayer Defendants knew, or should have known, that its product, Magnevist, was not reasonably fit, suitable or safe for its intended purpose, and specifically, that it was defective and unsafe for use in patients with renal insufficiency such as the Plaintiff, Scott Smith, and knew, or should have known, that the gadolinium contained in its product is highly toxic to humans. Further, at all times relevant hereto, the Bayer Defendants knew, or should have known, about the significant health risk of Magnevist administration to patients with renal insufficiency, including, but not limited to, the risk of toxic gadolinium being released into the bodies of those patients, causing severe physical injury.

51. Omniscan is an injectable paramagnetic contrast agent for magnetic resonance imaging and arteriography. It contains the metal gadolinium which is highly toxic in its free state. Omniscan, the chemical name of which is gadolinium diethylenetriamine pentaacetic acid bismethylamide (gadodiamide), is represented by the GE Defendants to be safely and

effectively indicated for intravenous administration to facilitate the visualization of lesions with abnormal vascularity.

52. Omniscan is cleared from the body solely by glomerular filtration in the kidneys. As a result, it has a prolonged half-life in patients with renal insufficiency and who, therefore, are at increased risk for adverse health effects in connection with Omniscan administration.

53. Omniscan was originally developed by Salutar, Inc. which then conducted pre-clinical testing with Sterling Winthrop and Daiichi Pharmaceuticals. Salutar was subsequently acquired by Nycomed. In 1994, Nycomed acquired Sterling Winthrop's diagnostic imaging business.

54. In 1997, Nycomed acquired Amersham International plc, and the new company was named Amersham plc, which then held the rights to Omniscan.

55. In 2004, General Electric Company acquired Amersham plc and the rights to Omniscan. At the time of the acquisition, Amersham plc was the ultimate parent company of Amersham Health AS, which manufactured the Omniscan that was distributed and sold in the United States, and Amersham Health Inc., which distributed and sold Omniscan in the United States. In 2006, Amersham Health AS was renamed GE Healthcare AS, and Amersham Health, Inc. was renamed GE Healthcare, Inc.

56. Defendants General Electric Company, GE Healthcare AS, and GE Healthcare, Inc. are corporate successors to Amersham plc and its related entities, and, as such, are obligated for their predecessor's liabilities. Amersham plc, either itself or by and

through its subsidiaries, was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into United States interstate commerce, directly and indirectly through third parties or related entities, the drug Omniscan.

57. Optimark is an injectable paramagnetic contrast agent used for magnetic resonance imaging and arteriography. It contains the metal gadolinium, which is highly toxic in its free state. Optimark, the chemical name of which is gadolinium diethylenetriamine pentaacetic acid bismethoxyethylamide (gadoversetamide), is represented by the Defendant Mallinckrodt to be safely and effectively indicated for intravenous administration to facilitate the visualization of lesions with abnormal vascularity.

58. MultiHance and ProHance are injectable paramagnetic contrast agents for magnetic resonance imaging and arteriography. They contain the metal gadolinium, which is highly toxic in its free state. Upon information and belief, MultiHance and ProHance were represented by the Bracco Defendants to be safely and effectively indicated for intravenous administration to facilitate visualization of lesions with abnormal blood brain barrier or abnormal vascularity of the brain, spine, and associated tissues.

59. At all times relevant hereto, the Defendants knew, or should have known, about the significant health risk of their products' administration to patients with renal insufficiency, including, but not limited to, the risk of nephrogenic fibrosis in the skin and other body organs. At all times relevant hereto, Defendants knew, or should have known, that, in its free state, gadolinium is highly toxic, harmful and dangerous to humans, and causes severe physical injury and knew, or should have known, of the need to prevent the

gadolinium contained in its product from becoming free in the body of humans injected with Omniscan, Magnevist, Optimark, and/or, upon information and belief, MultiHance and/or ProHance, through the use of, among other things, proper design, testing, and manufacturing.

60. At all relevant times, Defendants knew, or should have known, that there were safer, alternative designs for paramagnetic contrast agents that would prevent or minimize the risk of gadolinium becoming free in the bodies of humans and knew, or should have known, of safer, alternative designs for imaging systems, like those used by other leading MRI systems manufacturers, that do not use gadolinium based contrast agents, which would provide a safer imaging alternative for the public, including Scott Smith.

61. At all times relevant hereto, Defendants knew, or should have known, that their respective products, Omniscan, Magnevist, Optimark and/or upon information and belief, MultiHance and/or ProHance, were not reasonably fit, suitable or safe for their intended purpose and, specifically, that they were defective and unsafe for use in patients with renal insufficiency, such as Scott Smith, and knew, or should have known, that the gadolinium contained in its product is highly toxic to humans, and knew, or should have known, about the significant health risk of administration of these products to patients with renal insufficiency, including, but not limited to, the risk of toxic gadolinium being released into the bodies of those patients, causing severe physical injury.

62. Scott Smith was exposed to the gadolinium containing contrast dyes Omniscan, Magnevist, and upon information and belief, Optimark, ProHance and/or MultiHance, during imaging procedures at the University of Utah in 2003 and 2004.

63. After being administered Magnevist, Omniscan and, upon information and belief, Optimark, MultiHance and/or ProHance, gadolinium was released into his body. Scott Smith began experiencing symptoms of Nephrogenic Systemic Fibrosis (NSF), also known as Nephrogenic Fibrosing Dermopathy (NFD), after and because of these administrations.

64. NSF/NFD develops only in patients with renal insufficiency, such as Scott Smith, who have been given an injection of a gadolinium-based contrast agent such as Magnevist, Omniscan, Optimark, and/or upon information and belief, MultiHance and/or ProHance.

65. NSF/NFD is predominantly characterized by discoloration, thickening, tightening, and swelling of the skin within weeks after receiving a gadolinium-based contrast injection such as Magnevist, Omniscan, and/or upon information and belief, Optimark, MultiHance and/or ProHance. These symptoms can occur weeks or months after a person is administered these dyes. These fibrotic and edematous changes produce muscular weakness and inhibit flexion and extension of joints, resulting in contractures. NSF/NFD often progresses to painful inhibition of the ability to use the arms, legs, hands, feet, and other joints. The skin changes that begin as darkened patches or plaques progress to a "woody" texture and are accompanied by burning, itching, or severe pain in the areas of involvement. NSF/NFD also progresses to a fibrotic or scarring condition of other body organs such as the lungs, heart, liver, and musculature, and that can inhibit their ability to function properly and may lead to death. NSF/NFD is a progressive disease as to which there is no known cure.

66. The GE, Bayer, Mallinckrodt, and upon information and belief, Bracco Defendants consistently failed to warn consumers and/or their health care providers that severe, even fatal, injuries could result when their dyes are administered to patients with renal insufficiency.

67. During the years that the Defendants manufactured, marketed, and sold their respective products, there were numerous case reports, studies, assessments, papers, and other relevant experimental and clinical data that have described and/or demonstrated dissociation and transmetallation in connection with the use of certain gadolinium-based contrast agents. Despite this, the GE, Bayer, Mallinckrodt and, upon information and belief, Bracco Defendants repeatedly failed to adequately revise their package inserts, Material Safety Data Sheets, and other product-related literature, and to conduct appropriate post-marketing communications in order to convey adequate warnings.

68. The GE, Bayer, Mallinckrodt, and upon information and belief, Bracco Defendants repeatedly and consistently failed to advise consumers and/or their health care providers of the propensity of their products to undergo dissociation and transmetallation in vivo and of the causal relationship between certain gadolinium contrast dye and the development of NSF/NFD in patients with renal insufficiency.

69. Scott Smith suffers from debilitating and worsening fibrotic changes to his body as a result of contracting NSF/NFD.

70. As a direct and proximate result of being administered Magnevist, Omniscan and, upon information and belief, Optimark, MultiHance, and/or ProHance, Scott Smith

suffers serious, progressive, permanent, incurable, and potentially fatal injuries and Cindy Smith suffers a loss of consortium.

71. As a direct and proximate result of being administered Magnevist, Omniscan, Optimark, MultiHance, and/or ProHance, Scott Smith suffered, and continues to suffer, significant harm, conscious pain and suffering, physical injury, bodily impairment, disfigurement and scarring, including, but not limited to, suffering from NSF/NFD, amputation procedures, and systemic manifestations. Scott Smith further suffered and continues to suffer significant mental anguish and emotional distress, physical limitations, pain, injury, damages, and harm. Scott Smith has also incurred, and continues to incur, medical expenses and other economic harm as a direct and proximate result of being administered Magnevist, Omniscan, Optimark, MultiHance, and/or ProHance.

72. As a direct and proximate result of being administered gadolinium contrast dye, Plaintiff Scott Smith has incurred medical expenses and other economic harm and has further experienced limited mobility, dramatic life changes, severe and debilitating physical and emotional pain and distress, disfigurement and other non-economic harm, and Cindy Smith has suffered a loss of consortium.

73. The Defendants, upon information and belief, have, or may have, failed to comply with all federal standards and requirements applicable to the sale of their prescription drugs, Omniscan, Magnevist, Optimark, MultiHance and ProHance, including, but not limited to, one or more of the following violations:

a. The Defendants' prescription drugs are adulterated pursuant to 21 U.S.C. § 351 because, among other things, they fail to meet established performance standards, and/or the methods, facilities, or controls used for their manufacture, packing, storage or installation are not in conformity with federal requirements. See, 21 U.S.C. §351.

b. The Defendants' prescription drugs are adulterated pursuant to 21 U.S.C. § 351 because, among other things, their strength differs from or their quality or purity falls below the standard set forth in the official compendium for the drugs, and such deviation is not plainly stated on their labels.

c. The Defendants' prescription drugs are misbranded pursuant to 21 U.S.C. §352 because, among other things, their labeling is false or misleading.

d. The Defendants' prescription drugs are misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. The Defendants' prescription drugs are misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use in those

pathological conditions or by children where their use may be dangerous to health or against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users.

f. The Defendants' prescription drugs are misbranded pursuant to 21 U.S.C. §352 because they are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g. The Defendants' prescription drugs do not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which they are intended, including conditions, purposes, or uses for which they are prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which they are intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application.

h. The Defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.

i. The Defendants' prescription drugs are misbranded pursuant to 21 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j. The Defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drugs including degree and rate of absorption, pathways of biotransformation, percentage of dosage as unchanged drug and metabolites, rate or half-time of elimination, concentration in body fluids associated with therapeutic and/or toxic effects, degree of binding to plasma proteins, and/or the degree of update by a particular organ.

k. The Defendants violated 21 CFR § 201.57 because evidence was only available to support the safety and effectiveness of the drugs in selected subgroups of the larger population with a disease, syndrome, or symptom and the labeling failed to describe the available evidence and state the limitations of usefulness of the drugs.

l. The Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drugs.

m. The Defendants violated 21 CFR § 201.57 because the safety considerations regarding the prescription drugs are such that the drugs should be reserved for certain situations, and the Defendants failed to state such information.

n. The Defendants' prescription drugs are mislabeled pursuant to 21 CFR § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

o. The Defendants' prescription drugs are mislabeled pursuant to 21 CFR § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

p. The Defendants violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drugs and other drugs in the same pharmacologically active and chemically related class.

q. The Defendants violated 21 CFR § 201.57 because the possibility that a patient could develop NSF/NFD is significantly more severe than the other reactions listed in the adverse reactions, and, yet, the Defendants failed to list the development of NSF/NFD before the other adverse reactions on the labeling of the prescription drugs.

r. The Defendants' prescription drugs are mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

s. The Defendants' prescription drugs violate 21 CFR § 210.1 because the process by which they are manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that they meet the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.

t. The Defendants' prescription drugs violate 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

u. The Defendants' prescription drugs violate 21 CFR § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

v. The Defendants' prescription drugs violate 21 CFR § 211.165 in that the prescription drugs fail to meet established standards or specifications and any other relevant quality control criteria.

w. The Defendants' prescription drugs violate 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drugs were not followed.

x. The Defendants' prescription drugs violate 21 CFR § 310.303 in that the prescription drugs are not safe and effective for their intended use.

y. The Defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

z. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drugs as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drug experience.

aa. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drugs and evaluating the cause of the adverse event.

bb. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

cc. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

dd. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report follow-up."

ee. The Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drugs or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

ff. The Defendants violated 21 CFR § 312.32 because they failed to notify the FDA in a written IND safety report of the adverse experiences

associated with the use of the prescription drugs that were serious and unexpected.

gg. The Defendants violated 21 CFR § 314.80 by failing to report adverse drug experiences at quarterly intervals for three (3) years from the date of approval of the application, and then at annual intervals.

hh. The Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

ii. The Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

CAUSES OF ACTION AND CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION AND CLAIM FOR RELIEF
(Strict Products Liability-Failure to Warn)

74. Plaintiffs incorporate by reference the preceding paragraphs of the Complaint.

75. Defendants marketed and sold gadolinium based contrast agent and Defendants are in the business of marketing and selling gadolinium based contrast agents and other drugs. The foreseeable risks of this product exceeded the benefits associated with its design or formulation. Defendants knew or should have known of the defective condition, characteristics and risks associated with their product.

76. The gadolinium based contrast agents was sold to, expected to reach and did reach Plaintiff without any substantial change in the condition in which it was sold.

77. Defendants' gadolinium based contrast agents caused individuals to develop Nephrogenic Systemic Fibrosis but Defendants failed to adequately warn Scott Smith or his physicians.

78. Defendants' gadolinium based contrast agents in question are defective by virtue of their inadequate warning and are unreasonably dangerous products.

79. As a direct and proximate result of ingesting Defendants' gadolinium based contrast agents, unreasonably dangerous products, Scott Smith developed Nephrogenic Systemic Fibrosis and has suffered, and Plaintiffs will continue to suffer, other injuries, damages and losses as alleged herein, and Defendants are strictly liable.

80. Defendants have shown wanton disregard for the health, safety and welfare of others by its conduct.

WHEREFORE, Plaintiffs demand judgment against Defendants for Strict Products Liability - Failure to Warn as prayed for below.

SECOND CAUSE OF ACTION AND CLAIM FOR RELIEF
(Negligence)

81. Plaintiffs incorporate by reference the preceding paragraphs of the Complaint.

82. Defendants owed Plaintiffs a duty of care to reasonably and prudently provide proper warnings and to properly advertise, investigate, clinically study, test, label, manufacture, research, design, process, assemble, formulate, package and market Defendants' gadolinium based contrast agents.

83. Defendants breached their duty of care to Plaintiffs.

84. As a direct and proximate result of Defendants' negligence, Scott Smith contracted Nephrogenic Systemic Fibrosis, and Plaintiffs have suffered, and will continue to suffer, other injuries, damages and losses as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for Negligence as prayed for below.

THIRD CAUSE OF ACTION AND CLAIM FOR RELIEF
(Negligence *Per Se* against)

85. Plaintiffs incorporate by reference the preceding paragraphs of the Complaint.

86. Defendants owed Plaintiffs a duty of care imposed by law pursuant to C.F.R. 201.57(f) to warn of serious adverse reactions and potential safety hazards in Defendants' gadolinium based contrast agents' labeling. Defendants also owed duties imposed by 21 U.S.C. Sec. 301 et seq. Plaintiffs are within the class of purchasers that these statutes sought to protect.

87. Nephrogenic Systemic Fibrosis is a serious adverse reaction and potential safety hazard that can result from receipt of Defendants' gadolinium based contrast agents.

88. Defendants' labeling for Defendants' gadolinium based contrast agents, at all times relevant herein, did not warn that Nephrogenic Systemic Fibrosis is a serious adverse reaction and potential safety hazard associated with receiving Defendants' gadolinium based contrast agents.

89. Defendants breached their duty of care to Plaintiffs by violating C.F.R. 201.57(f).

90. As a direct and proximate result of Defendants' negligence *per se*, Scott Smith developed Nephrogenic Systemic Fibrosis, and Plaintiffs have suffered, and will continue to suffer, other injuries, damages and losses as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for Negligence *Per Se* as prayed for below.

FOURTH CAUSE OF ACTION AND CLAIM FOR RELIEF
(Negligent Misrepresentation)

91. Plaintiffs incorporate by reference the preceding paragraphs of the Complaint.

92. Defendants, in the course of their business profession, supplied Scott Smith, his wife and his physician with false information for guidance in their decision to select gadolinium based contrast agents.

93. The false information supplied by Defendants to Scott Smith, and his physician and other healthcare providers, was that Defendants' gadolinium based contrast agents were safe and effective and would not adversely affect Scott Smith's health.

Defendants made the forgoing representations without reasonable ground to believe them to be true. Previous studies by Defendants indicated to them that they knew or should have known that the products could not be safely given to the renally impaired individuals.

94. The false information obtained and communicated to Scott Smith, his wife and his physicians was material, made with the intention of inducing reliance, and was justifiably relied by Plaintiffs in good faith on the information to their detriment.

95. As a result of the negligent misrepresentation of Defendants, Plaintiffs suffered, and will continue to suffer, injuries, damages and losses as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for Negligent Misrepresentation as prayed for below.

FIFTH CAUSE OF ACTION AND CLAIM FOR RELIEF
(Breach of Implied Warranty)

96. Plaintiffs incorporate by reference the preceding paragraphs of the Complaint.

97. Plaintiffs, by and through their health care providers, purchased Defendants' gadolinium based contrast agents.

98. Defendants impliedly warranted that gadolinium based contrast agents were of merchantable quality and safe and fit for the use for which they were intended.

99. Scott Smith and his wife are unskilled in the research, design, formulation, compounding, testing, manufacturing, production, processing, assembling, inspection, distribution, marketing, labeling, promotion, packaging and advertising of gadolinium based contrast products and relied on the skill and judgment and implied warranty of Defendants

that Defendants' gadolinium based contrast agents were of merchantable quality and safe and fit for the use for which they were intended. Failing to do also means that Defendants violated the Utah Code which requires an implied warranty of merchantability along with provisions of Article II of the Uniform Commercial Code.

100. Gadolinium based contrast agents were not of merchantable quality and not safe or fit for the use for which they were intended in that they had dangerous propensities when put to their intended use and would cause severe injuries to the users, including Scott Smith.

101. As a result of the breach of implied warranty by Defendants, Plaintiffs suffered, and will continue to suffer, injuries, damages and losses as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for Breach of Implied Warranty as prayed for below.

SIXTH CAUSE OF ACTION AND CLAIM FOR RELIEF
(Breach of Express Warranty)

102. Plaintiffs incorporate by reference the preceding paragraphs of the Complaint.

103. Plaintiffs, by and through their health care providers, purchased Defendants' gadolinium based contrast agents.

104. Defendants expressly warranted that Defendants' gadolinium based contrast agents were safe, effective, fit and proper for the use for which they were intended.

105. Scott Smith and his health care providers relied on the skill and judgment and express warranties of Defendants that Defendants' gadolinium based contrast agents were of safe, effective, fit and proper for the use for which they were intended.

106. The express warranties were untrue, false and inaccurate in that Defendants' gadolinium based contrast agents were not safe, effective, fit nor proper for the use for which they were intended.

107. As a result of the breach of express warranty by Defendants, Plaintiffs suffered, and will continue to suffer, injuries, damages and losses as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for Breach of Express Warranty as prayed for below.

SEVENTH CAUSE OF ACTION AND CLAIM FOR RELIEF
(Strict Products Liability - Defective Design)

108. Plaintiffs incorporate by reference the preceding paragraphs of the Complaint.

109. Defendants were engaged in the business of selling gadolinium based contrast agents for resale, use or consumption.

110. Defendants designed and manufactured Defendants' gadolinium based contrast agents.

111. Defendants' gadolinium based contrast agents sold to Plaintiffs were expected and did reach Plaintiffs without any substantial change in the condition in which they were sold.

112. The design of Defendants' gadolinium based contrast agents, when sold, was defective, and this defect made Defendants' gadolinium based contrast agents unreasonably dangerous for those reasonably expected to use or consume Defendants' gadolinium based contrast agents, such as Scott Smith. The foreseeable risks of this product exceeded the

benefits associated with its design or formulation. Further, safer reasonable alternatives existed for the design of such a medication.

113. This design defect caused injury to Plaintiffs, and Defendants are strictly liable for these injuries.

WHEREFORE, Plaintiffs demand judgment against Defendants for Strict Products Liability - Defective Design as prayed for below.

EIGHTH CAUSE OF ACTION AND CLAIM FOR RELIEF
(Strict Products Liability - Defective Manufacture)

114. Plaintiffs incorporate by reference the preceding paragraphs of the Complaint.

115. Defendants were engaged in the business of selling Defendants' gadolinium based contrast agents for resale, use or consumption.

116. Defendants designed and manufactured Defendants gadolinium based contrast agents.

117. Defendants marketed and sold Defendants' gadolinium based contrast agents and are in the business of marketing and selling Defendants' gadolinium based contrast agents and other drugs.

118. Defendants' gadolinium based contrast agents sold to Plaintiffs was expected and did reach Plaintiffs without any substantial change in the condition in which it was sold.

119. The manufacture of Defendants' gadolinium based contrast agents was defective, and this defect made Defendants' gadolinium based contrast agents unreasonably dangerous for those reasonably expected to use or consume Defendants' gadolinium based contrast agents, such as Scott Smith.

120. This manufacturing defect caused injury to Plaintiffs, and Defendants are strictly liable for these injuries.

WHEREFORE, Plaintiffs demand judgment against Defendants for Strict Products Liability - Defective Manufacture as prayed for below.

NINTH CAUSE OF ACTION AND CLAIM FOR RELIEF
(Strict Products Liability - Defective Inspection/Testing)

121. Plaintiffs incorporate by reference the preceding paragraphs of the Complaint.

122. Defendants were engaged in the business of selling Defendants' gadolinium based contrast agents for resale, for use.

123. Defendants designed and manufactured Defendants' gadolinium based contrast agents.

124. Defendants marketed and sold Defendants' gadolinium based contrast agents and are in the business of marketing and selling Gadolinium based contrast agents and other drugs.

125. Defendants' gadolinium based contrast agents sold to Plaintiffs or healthcare providers were expected and did reach Plaintiffs without any substantial change in the condition in which they were sold.

126. The testing and/or inspection of Defendants' gadolinium based contrast agents was defective, and this defect made Defendants' gadolinium based contrast agents unreasonably dangerous for those reasonably expected to use Defendants' gadolinium based contrast agents, such as Scott Smith.

127. These defects caused injury to Plaintiffs, and Defendants are strictly liable for these injuries.

WHEREFORE, Plaintiffs demand judgment against Defendants for Strict Products Liability - Defective Testing/Inspection as prayed for below.

TENTH CAUSE OF ACTION AND CLAIM FOR RELIEF
(Violation of Utah Consumer Sales Practice Act)

128. Plaintiffs incorporate by reference the preceding paragraphs of this Complaint.

129. Plaintiffs bring this cause of action and claim for relief pursuant to the Utah Consumer Sales Practices Act and respectfully request that the Court award all appropriate remedies provided in the prayer.

130. The acts described in the previous paragraphs constitute a deceptive act or practice and/or and unconscionable act or practice by Defendants, and thus, violates the Utah Consumer Sales Practice Act, in the following particulars, among others: a) representing to physicians and others that their product was safe; b) purposefully downplaying health hazards; and c) manipulating studies that would suggest that the products were unsafe.

131. The violation of the Utah Consumers Sales Practices Act by Defendants, as described above, represents a continuing threat to members of the public in that Defendants continue to engage in the conduct described therein.

132. Plaintiffs, pursuant to the Utah Consumer Sales Practices Act, seek an order of this court that the acts or practices of Defendants violate this law and Defendants are enjoined, in accordance with the principles of equity, from violating this law, and, further,

that Plaintiffs are entitled to their actual damages or $2000, whichever is greater, plus court costs.

ELEVENTH CAUSE OF ACTION AND CLAIM FOR RELIEF
(Loss of Consortium)

133. Plaintiffs incorporate by reference the preceding paragraphs of this Complaint.

134. Plaintiff Cindy Smith, was at all relevant times and continues to be, the spouse of Plaintiff Scott Smith.

135. At all relevant times, Cindy Smith was entitled to the services and society of his spouse and was responsible for the care, maintenance and medical expenses for his spouse.

136. As a direct and proximate result of the actions described above, Scott Smith has not been able to perform his job or do the necessary chores for his family to care for his family that would otherwise be required from him. Further, the actions above have had the direct and proximate result of a loss of love, companionship and other consortium.

WHEREFORE, Plaintiffs demand judgment against Defendants for loss of consortium as prayed for below.

TWELFTH CAUSE OF ACTION AND CLAIM FOR RELIEF
(Punitive Damages)

137. Plaintiffs incorporate by reference the preceding paragraphs of this Complaint.

138. Defendants engaged in intentional, willful, wanton, and reckless conduct with conscious disregard for the safety of consumers including Plaintiffs in the manner and for the reasons set forth above.

139. Further, Defendant knew of their products' defective nature but continued to design, manufacture, market and sell the products to maximize profits at the expense of public safety.

WHEREFORE, Plaintiffs demand judgment against Defendants for punitive damages as prayed for below.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

A. General damages, past and future, including, but not limited to, pain and suffering, mental anguish, physical disfigurement, emotional distress and loss of enjoyment of life;

B. Special damages, past and future, including, but not limited to, medical, incidental, hospital, service and rehabilitation;

C. Loss of earnings and/or earnings capacity and other economic losses, past and future, and all other pecuniary losses;

D. Loss of consortium;

E. Punitive Damages;

F. Pre-judgment and post-judgment interest as provided for by law;

G. Attorneys' fees, costs and expenses of this action as provided for by law; and

H. For such other and further relief as the Court deems just and proper.

JURY TRIAL DEMAND

Plaintiffs hereby demand a trial by jury on all issues so triable.

Respectfully submitted this 6th day of May, 2008.

Douglas B. Cannon
FABIAN & CLENDENIN
Attorneys for Plaintiffs

ND: 4847-6327-3474, v. 1